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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/552,461 04/18/00 KOKOLUS

W WKP:101(B) U

021807 HM22/0913
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EXAMINER

ZEMAN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/552,461	Applicant(s) KOKOLUS, WILLIAM J.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 13-18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group V, claims 12 and 19 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the restriction between groups I, II and IV is improper. This is not found persuasive because these arguments are not directed to rejoinder with the elected group (Group V) and are therefore not germane to that election. No arguments are specifically set forth in regard to Group V and any other group. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-11, 13-18 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Priority

Applicant is requested up update the statement of priority in the specification to reflect the issuance of a patent of a parent application.

Information Disclosure Statement

The IDS filed with the application has been entered. The examiner was unable to obtain copies of the cited references from the parent application. The US Patent listed thereon has been considered. Applicant is requested to submit copies of the journal articles listed on the form PTO-1449, as soon as possible. A new form PTO-1449 is not required, nor should any fee be charged for the submission of those copies.

Claim Rejections - 35 USC § 112

Claims 12 and 19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 19 are indefinite because they depend from a non-elected claim. Each claim should be amended to incorporate all the limitations of the claims from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 12 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kokolus et al. (WO 96/40754).

The claims are drawn to diagnostic immunoassays wherein antibodies specific to an antigen are used to detect an antigen in a sample. It should be noted that the product-by-process limitations on the antibody do not materially affect the nature of that antibody and therefore any antibody capable of binding the same antigen would meet that limitation of the claim.

Kokolus et al. (WO 96/40754 A1, 19 December 1996) discloses a diagnostic immunoassay to a prostate specific antigen. Antisera specific for an epitope of PSA (pages 21-31) are used in various immunoassay formats for the diagnosis of prostate disease (pages 31-39). While the product-by-process limitations are not given patentable weight, as set forth above, it should be noted that Kokolus et al. perform the same analyses on the PSA sequence in order to obtain a peptide of optimum length, with the proper hydrophobic-hydrophilic-hydrophobic characteristics. (See pages 4-6, 40-44, etc.) A large number of other antigens from various categories are contemplated, including lymphokines, hormones, tumor markers, tumor antigens, oncogenes, complement proteins, and viral proteins.

Claims 12 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Kokolus et al. (US Patent 5,807,978).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing

under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Kokolus et al. (US Patent 5,807,978) discloses a diagnostic immunoassay to a prostate specific antigen. Antisera specific for an epitope of PSA (columns 11-15) are used in various immunoassay formats for the diagnosis of prostate disease (columns 16-19). While the product-by-process limitations are not given patentable weight, as set forth above, it should be noted that Kokolus et al. perform the same analyses on the PSA sequence in order to obtain a peptide of optimum length, with the proper hydrophobic-hydrophilic-hydrophobic characteristics. (See columns 4-5, 20-23, etc.) A large number of other antigens from various categories are contemplated, including lymphokines, hormones, tumor markers, tumor antigens, oncogenes, complement proteins, and viral proteins (column 7).

Claims 12 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Dowell et al. (US Patent 5,599,677).

Dowell et al. (US Patent 5,599,677) disclose immunoassays using antibodies specific to an antigen. The specific antigen disclosed is PSA. The antibodies are generated against PSA protein and would be expected to be specific for a particular epitope of PSA.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6,070,126, Kokolus et al. Is the issued patent from the parent application.

Van Oss, Molecular Immunology, 1995, Vol. 32 No. 3 pages 119-211. This document discusses the hydrophilic and hydrophobic interactions between an antibody and an antigen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can generally be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
9/6/01

Mary K. Zeman
MARY K. ZEMAN
PATENT EXAMINER
1631